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MERCK & CO., INC.

7
8 **UNITED STATES DISTRICT COURT**
9 **SOUTHERN DISTRICT OF CALIFORNIA**

10
11 EDNA GOYA, an individual

12 Plaintiff,

13 v.

14 MERCK & CO., INC., a Corporation;
McKESSON CORPORATION, a
15 Corporation; and DOES 1-100, inclusive,

16 Defendants.
17
18
19

CASE NO.: 06-CV-2574 H (AJB)

**DEFENDANT MERCK & CO.,
INC.'S ANSWER TO COMPLAINT
AND DEMAND FOR JURY TRIAL**

20 Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned
21 attorneys, hereby answers those allegations of Plaintiff's Complaint directed to it. To
22 the extent the allegations of any paragraph are directed at McKesson Corporation,
23 Merck is not required to respond to those allegations. To the extent a response is
24 deemed necessary, Merck states that it denies all such allegations, except those that are
25 specifically admitted below. In addition, Merck denies all allegations set forth in the
26 Complaint directed at Merck except to the extent such allegations are specifically
27 admitted below:
28

INTRODUCTION

Merck denies each and every allegation made in the Introduction, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® and avers that FOSAMAX® is a prescription medication approved by the Federal Food and Drug Administration ("FDA") for prescription in accordance with its approved prescribing information.

GENERAL ALLEGATIONS

1. Merck denies each and every allegation of Paragraph 1, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and that Plaintiff purports to bring a civil action for damages, but denies that there is any legal or factual basis for the same. Further, Merck states that it is without knowledge or information sufficient to form a belief as to whether Plaintiff has been prescribed, supplied with, received, took, ingested, or consumed FOSAMAX®.

2. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 2.

3. The allegations of Paragraph 3 do not require a response. To the extent that a response is deemed necessary, Merck denies each and every allegation of Paragraph 3.

4. Merck denies each and every allegation of Paragraph 4.

5. Merck denies each and every allegation of Paragraph 5.

6. Merck denies each and every allegation of Paragraph 6.

7. Upon information and belief, Merck admits that McKesson Corporation's principal place of business is located in San Francisco, California, but denies that McKesson Corporation is a proper party to this litigation. Merck denies any remaining allegations of Paragraph 7.

8. Upon information and belief, Merck admits that McKesson Corporation's principal place of business is located in San Francisco, California, but denies that

McKesson Corporation is a proper party to this litigation. Merck denies any remaining allegations of Paragraph 8.

9. Merck denies each and every allegation of Paragraph 9, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

10. Merck denies each and every allegation of Paragraph 10, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and admits that it is registered to do business in California.

11. Merck denies each and every allegation of Paragraph 11.

12. Merck denies each and every allegation of Paragraph 12.

THE PARTIES

The Plaintiff

13. Merck denies each and every allegation of Paragraph 13, except that it states that it lacks knowledge or information sufficient to form a belief as to the residence of Plaintiff and whether she took FOSAMAX®.

The Defendants

14. Merck denies each and every allegation of Paragraph 14, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

15. Merck denies each and every allegation of Paragraph 15, except that it admits that it is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in Whitehouse Station, New Jersey, and admits that it is registered to do business in California.

16. Upon information and belief, Merck admits that McKesson Corporation's principal place of business is in San Francisco, California. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 16, except that Merck denies that McKesson Corporation

1 promotes FOSAMAX®.

2 17. Merck lacks knowledge or information sufficient to form a belief as to the
3 truth or falsity of the allegations of Paragraph 17.

4 **FACTUAL BACKGROUND**

5 18. Merck denies each and every allegation in Paragraph 18, except that Merck
6 admits that it sought and, in 1995, first obtained FDA approval to manufacture and
7 market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription
8 medication approved by the FDA for prescription in accordance with its approved
9 prescribing information. Merck denies any allegations in Paragraph 18 inconsistent
10 with that prescribing information and respectfully refers the Court to the Physician's
11 Desk Reference ("PDR") for FOSAMAX® for its actual language and full text.

12 19. Merck denies each and every allegation of Paragraph 19, except that
13 Merck admits that FOSAMAX® is a prescription medication approved by the FDA for
14 prescription in accordance with its approved prescribing information. Merck denies any
15 allegations in Paragraph 19 inconsistent with that prescribing information and
16 respectfully refers the Court to the PDR for FOSAMAX® for its actual language and
17 full text, including its sections on pharmacodynamics and mechanism of action.

18 20. The allegations of Paragraph 20 merely restate information taken from the
19 website of the National Osteoporosis Foundation and are not directed at Merck.
20 Consequently, no response is required. To the extent a response is required, Merck
21 states that the statistics presented on the National Osteoporosis Foundation website
22 speak for themselves, and Merck denies any allegation of Paragraph 20 directed to
23 Merck.

24 21. The allegations of the first sentence Paragraph 21 merely restate
25 information taken from the website of Business Week Online and are not directed at
26 Merck. Consequently, no response is required. To the extent a response is required,
27 Merck states that the information presented on the Business Week Online website
28 speaks for itself, and Merck denies any allegation of the first sentence of Paragraph 21

1 directed to Merck. Merck denies each and every allegation of the second sentence of
2 Paragraph 21, except admits that in 2005, Merck reported that FOSAMAX® recorded
3 the second highest sales in its line of therapeutic and preventative agents and admits
4 that FOSAMAX® is the most prescribed medicine for the treatment of postmenopausal,
5 male and glucocorticoid-induced osteoporosis.

6 22. The allegations of the first two sentences of Paragraph 22 merely restate
7 information taken from the website of IMS Health. Consequently, no response is
8 required. To the extent a response is required, Merck states that the information
9 presented on the IMS Health website speaks for itself, and Merck denies any allegation
10 of the first two sentences of Paragraph 22 directed to Merck. As to the allegations of
11 the third sentence of Paragraph 22, Merck states that the information presented on the
12 Consumer Reports website speaks for itself, and Merck denies any allegation of the
13 third sentence of Paragraph 22 directed to Merck. Merck denies each and every
14 allegation of the fourth sentence of Paragraph 22, except admits that it obtained
15 approval from the FDA for FOSAMAX PLUS D® in 2005 and admits that the
16 language quoted therein appears in Merck's 2005 Annual Report.

17 23. Merck admits only that some bisphosphonates contain nitrogen and some
18 do not and denies all remaining allegations of Paragraph 23.

19 24. Merck admits only that FOSAMAX® is a prescription medication
20 approved by the FDA for prescription in accordance with its approved prescribing
21 information. Merck denies any allegations in Paragraph 24 inconsistent with that
22 prescribing information and respectfully refers the Court to the PDR for FOSAMAX®
23 for its actual language and full text. Merck denies any remaining allegations of
24 Paragraph 24.

25 25. Merck denies each and every allegation of Paragraph 25, except that
26 Merck admits that beginning in approximately late 2003, there have been articles about
27 patients reported to be on bisphosphonate therapy and the relatively uncommon
28 occurrence of osteonecrosis of the jaw. Further, Merck avers that the articles speak for

1 themselves, and specifically denies that FOSAMAX® causes or contributes to
2 osteonecrosis of the jaw.

3 26. Merck denies each and every allegation of Paragraph 26.

4 27. Merck denies each and every allegation of Paragraph 27.

5 28. Merck denies each and every allegation of Paragraph 28.

6 29. Merck denies each and every allegation of Paragraph 29.

7 30. Merck denies each and every allegation of Paragraph 30, except that
8 Merck admits that the FDA drafted an “ODS Postmarketing Safety Review,” but
9 respectfully refers the Court to said document for its actual language and full text.

10 31. Merck denies each and every allegation of Paragraph 31, except that
11 Merck admits that on January 31, 2005, it received a request dated January 24, 2005
12 from the FDA to update the label for FOSAMAX® to include bisphosphonate class
13 labeling for ONJ. Merck submitted a draft revised label to the FDA on March 1, 2005.
14 FDA comments on this draft revised label were received in June 2005, and the new
15 label was made publicly available in July 2005.

16 32. Merck denies each and every allegation of Paragraph 32.

17 33. Merck denies each and every allegation of Paragraph 33.

18 34. Merck denies each and every allegation of Paragraph 34, except that
19 Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX® by
20 her physician and whether Plaintiff ingested FOSAMAX® as prescribed and in a
21 foreseeable manner.

22 35. Merck denies each and every allegation of Paragraph 35.

23 36. Merck denies each and every allegation of Paragraph 36.

24 37. Merck denies each and every allegation of Paragraph 37.

25 38. Merck denies each and every allegation of Paragraph 38.

26 **FIRST CAUSE OF ACTION**
27 **STRICT LIABILITY – FAILURE TO WARN**
28 **(Against All Defendants)**

39. Merck repleads its answers to Paragraphs 1 through and including 38, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

40. Merck denies each and every allegation of Paragraph 40, except that it admits that Merck manufactured and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44, including each and every allegation of subparts (a) through (c).

SECOND CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

45. Merck repleads its answers to Paragraphs 1 through and including 44, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

46. The allegations in Paragraph 46 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48, including each and every allegation of subparts (a) through (e).

49. Merck denies each and every allegation of Paragraph 49.

50. Merck denies each and every allegation of Paragraph 50.

51. Merck denies each and every allegation of Paragraph 51.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(Against All Defendants)

52. Merck repleads its answers to Paragraphs 1 through and including 51, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

53. Merck denies each and every allegation of Paragraph 53, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

54. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 54.

55. Merck denies each and every allegation of Paragraph 55.

56. Merck denies each and every allegation of Paragraph 56.

57. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against All Defendants)

60. Merck repleads its answers to Paragraphs 1 through and including 59, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

61. Merck denies each and every allegation of the first sentence of Paragraph 61, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is

a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the second sentence of Paragraph 61.

62. Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the first sentence of Paragraph 62. Merck denies each and every allegation of the second sentence of Paragraph 62, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

63. Merck denies each and every allegation of Paragraph 63.

64. Merck denies each and every allegation of Paragraph 64.

FIFTH CAUSE OF ACTION

(DECEIT BY CONCEALMENT – Cal. Civ. Code §1709 - 1710)

(Against All Defendants)

65. Merck repleads its answers to Paragraphs 1 through and including 64, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67, except that Merck avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

68. Merck denies each and every allegation of Paragraph 68, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein.

69. Merck denies each and every allegation of Paragraph 69.

70. Merck denies each and every allegation of Paragraph 70.

71. Merck denies each and every allegation of Paragraph 71.

SIXTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

(Against All Defendants)

72. Merck repleads its answers to Paragraphs 1 through and including 71, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

73. Merck denies each and every allegation of Paragraph 73.

74. Merck denies each and every allegation of Paragraph 74.

75. Merck denies each and every allegation of Paragraph 75.

76. Merck denies each and every allegation of Paragraph 76.

77. Merck denies each and every allegation of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

SEVENTH CAUSE OF ACTION
VIOLATION OF BUSINESS & PROFESSION

CODE SECTION 17200

(Against All Defendants)

79. Merck repleads its answers to Paragraphs 1 through and including 78, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

80. Merck denies each and every allegation of Paragraph 80.

81. Merck admits that Plaintiff brings this action seeking various forms of relief, but denies that there is any legal or factual basis for same and denies any remaining allegations of Paragraph 81.

82. The allegations in Paragraph 82 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied, and Merck respectfully refers the Court to California Business & Professional Code Section 17200 for its actual language and full text.

83. Merck denies each and every allegation of Paragraph 83, including each and every allegation contained in subparts (a) through (d).

84. Merck denies each and every allegation of Paragraph 84.

85. Merck denies each and every allegation of Paragraph 85.

86. Merck denies each and every allegation of Paragraph 86.

87. Merck denies each and every allegation of Paragraph 87.

88. Merck denies each and every allegation of Paragraph 88, and denies that there is any legal or factual basis for issuing any order seeking the relief requested by Plaintiff.

EIGHT CAUSE OF ACTION

VIOLATION OF BUSINESS & PROFESSION

CODE SECTION 17500

(Against All Defendants)

89. Merck repleads its answers to Paragraphs 1 through and including 88, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

90. Merck denies each and every allegation of Paragraph 90.

91. Merck admits that Plaintiff brings this action seeking various forms of relief, but denies that there is any legal or factual basis for same and denies any remaining allegations of Paragraph 91.

92. The allegations in Paragraph 92 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied, and Merck respectfully refers the Court to California Business & Professional Code Section 17500 for its actual language and full text.

93. Merck denies each and every allegation of Paragraph 93, including each and every allegation contained in subparts (a) through (d).

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97, and denies that there is any legal or factual basis for issuing any order seeking the relief requested by Plaintiff.

98. Merck admits that Plaintiff brings this action seeking various forms of relief, but denies that there is any legal or factual basis for same and denies any remaining allegations of Paragraph 98.

NINTH CAUSE OF ACTION
VIOLATION OF THE CONSUMER LEGAL REMEDIES ACT –
CIVIL CODE SECTION 1750 ET SEQ.

(Against All Defendants)

99. Merck repleads its answers to Paragraphs 1 through and including 98, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

100. Merck denies each and every allegation of Paragraph 100.

101. Merck admits that Plaintiff brings this action seeking various forms of relief, but denies that there is any legal or factual basis for same and denies any remaining allegations of Paragraph 101.

102. The allegations in Paragraph 102 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied, and Merck respectfully refers the Court to the Consumer Legal Remedies Act ("CLRA") for its actual language and full text.

103. The allegations in Paragraph 103 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied, and Merck respectfully refers the Court to the CLRA for its actual language and full text.

104. Merck denies each and every allegation of Paragraph 104.

105. Merck denies each and every allegation of Paragraph 105, including each

and every allegation of subparts (a) through (d).

106. Merck denies each and every allegation of Paragraph 106.

107. Merck denies each and every allegation of Paragraph 107.

108. Merck denies each and every allegation of Paragraph 108.

109. Merck admits that Plaintiff brings this action seeking various forms of relief, but denies that there is any legal or factual basis for same and denies any remaining allegations of Paragraph 109.

ELEVENTH CAUSE OF ACTION

MEDICAL MONITORING; INJUNCTIVE AND EQUITABLE RELIEF

(Against All Defendants)

[Note: There is no tenth cause of action in the Complaint]

110. Merck repleads its answers to Paragraphs 1 through and including 109, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

111. Merck denies each and every allegation of Paragraph 111.

112. Merck denies each and every allegation of Paragraph 112, including each and every allegation of subparts (a) through (d).

113. Merck denies each and every allegation of Paragraph 113.

114. Merck denies each and every allegation of Paragraph 114.

Merck denies that Plaintiff is entitled to any of the relief requested in her Prayer for relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon

completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such

injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault.

NINTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff relies upon any theory of breach of warranty, such

claims are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was

1 unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the
2 product exceeded any apparent risk given the scientific knowledge available when the
3 product was marketed.

4 **TWENTY-NINTH AFFIRMATIVE DEFENSE**

5 Merck's advertisements and labeling with respect to the products which are the
6 subject matter of this action were not false or misleading and, therefore, constitute
7 protected commercial speech under the applicable provisions of the United States and
8 California Constitutions.

9 **THIRTIETH AFFIRMATIVE DEFENSE**

10 The public interest in the benefit and availability of the product which is the
11 subject matter of this action precludes liability for risks, if any, resulting from any
12 activities undertaken by Defendant, which were unavoidable given the state of human
13 knowledge at the time those activities were undertaken. With respect to Plaintiff's
14 claims, if it is determined there is a risk inherent in the product which is the subject
15 matter of this action, then such risk, if any, is outweighed by the benefit of the product.

16 **THIRTY-FIRST AFFIRMATIVE DEFENSE**

17 At all times relevant herein, any product which is the subject matter of this action
18 manufactured and distributed by Merck in any state in the United States was
19 manufactured and distributed in a reasonable and prudent manner based upon available
20 medical and scientific knowledge and further was processed and distributed in
21 accordance with and pursuant to all applicable regulations of the FDA.

22 **THIRTY-SECOND AFFIRMATIVE DEFENSE**

23 With respect to each and every purported cause of action, the acts of Merck were
24 at all times done in good faith and without malice.

25 **THIRTY-THIRD AFFIRMATIVE DEFENSE**

26 To the extent there were any risks associated with the use of the product which is
27 the subject matter of this action which Merck knew or should have known and which
28 gave rise to a duty to warn, Merck at all times discharged such duty through appropriate

and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff has not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claimed are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

FORTIETH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injury or loss as alleged in the Complaint, such injury or loss may have been caused by parties other than answering defendant, or third persons not parties to this action, who may have been negligent, legally responsible, or otherwise at fault. In the event of a finding of liability in favor of Plaintiff, a settlement, or a judgment against answering defendant, answering defendant requests an apportionment of fault among all parties and third persons as permitted by *Li v. Yellow Cab Company* and *America Motorcycle Association v. Superior Court*. Answering defendant also requests a judgment and declaration of partial indemnification and contribution against all other parties or third persons in accordance with the apportionment of fault.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims under Business and Professions Code Sections 17200, et seq. and 17500, et seq. are barred in whole or in part because answering defendant's conduct

and all activities with respect to the subject pharmaceutical product manufactured or distributed by answering defendant were lawful, fair, truthful, not misleading or deceptive, and were justified based on the state of medical and scientific knowledge available during the relevant time period.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims under Business and Professions Code Sections 17200, et seq. and 17500, et seq. are barred in whole or in part because all of answering defendant's activities as alleged in the Complaint were in compliance with the applicable laws, regulations, and rules, and thus cannot be deemed unlawful, unfair, fraudulent, deceptive, untrue, or misleading.

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims under Business and Professions Code Sections 17200, et seq. and 17500, et seq. are barred in whole or in part because Plaintiff do not qualify as a private attorney general, and for that reason and others, Plaintiff lacks standing to prosecute a claim for injunctive or monetary relief.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims under Business and Professions Code Sections 17200, et seq. and 17500, et seq. are barred in whole or in part because there is no basis for injunctive relief in this action.

FORTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims under Business and Professions Code Sections 17200, et seq. and 17500 et seq. are barred in whole or in part by the doctrine of primary jurisdiction in that the subject pharmaceutical product manufactured or distributed by answering defendant and any advertisement regarding such product are regulated by the Food and Drug Administration and as such, answering defendant requests that this court, sitting in equity, abstain from hearing claims under Sections 17200 et seq. and 17500 et seq.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to relief under Business and Professions Code Sections

1 17200, et seq. and 17500 et seq. because Plaintiff has an adequate remedy at law.

2 **FORTY-SEVENTH AFFIRMATIVE DEFENSE**

3 Plaintiff's claims under Business and Professions Code Sections 17200, et seq.
4 and 17500 et seq. are barred in whole or in part under principles of substantive and
5 procedural due process.

6 **FORTY-EIGHTH AFFIRMATIVE DEFENSE**

7 Plaintiff's claims which are based on allegations of fraud have not been plead
8 with sufficient particularity.

9 **FORTY-NINTH AFFIRMATIVE DEFENSE**

10 Any statute which the Plaintiff claims applies in this case was not intended to
11 prevent against the harm allegedly suffered by the Plaintiff.

12 **PRAYER FOR RELIEF**

13 WHEREFORE, Merck prays as follows:

- 14 1. That Plaintiff takes nothing by the Complaint;
15 2. That this action be dismissed with prejudice;
16 3. That Merck be awarded its costs of suit herein, and its attorney's fees to
17 the extent provided for by statute or contract;
18 4. For such other and further relief as the Court deems just and proper.

19
20 Dated: November 29, 2006

21 VENABLE LLP
22 DOUGLAS C. EMHOFF
23 JEFFREY M. TANZER

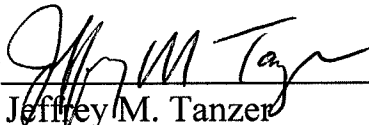
24
25 By Jeffrey M. Tanzer
26 Jeffrey M. Tanzer
27 Attorneys for Defendant
28 Merck & Co., Inc.

DEMAND FOR JURY TRIAL

Merck demands a trial by jury as to all issues so triable.

Dated: November 29, 2006

VENABLE LLP
DOUGLAS C. EMHOFF
JEFFREY M. TANZER

By 
Jeffrey M. Tanzer
Attorneys for Defendant
Merck & Co., Inc.

VENABLE LLP
2049 CENTURY PARK EAST, #2100
LOS ANGELES, CALIFORNIA 90067
(310) 229-9900

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 2049 Century Park East, #2100, Los Angeles, California 90067.

On November 29, 2006, I served the foregoing document(s) described as **DEFENDANT MERCK & CO., INC.'S ANSWER TO COMPLAINT AND DEMAND FOR JURY TRIAL** on the interested parties in this action addressed as follows:

SEE ATTACHED SERVICE LIST

☒ By placing true copies thereof enclosed in a sealed envelope(s) addressed as stated above.

☐ **BY PERSONAL SERVICE (CCP §1011):** I delivered such envelope(s) by hand to the addressee(s) as stated above.

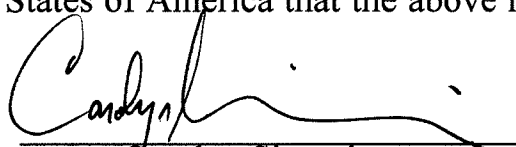
☒ **BY MAIL (CCP §1013(a)&(b)):** I am readily familiar with the firm's practice of collection and processing correspondence for mailing with the U.S. Postal Service. Under that practice such envelope(s) is deposited with the U.S. postal service on the same day this declaration was executed, with postage thereon fully prepaid at 2049 Century Park East, #2100 Los Angeles, California, in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY (CCP §1013(c)&(d)):** I am readily familiar with the firm's practice of collection and processing items for delivery with Overnight Delivery. Under that practice such envelope(s) is deposited at a facility regularly maintained by Overnight Delivery or delivered to an authorized courier or driver authorized by Overnight Delivery to receive such envelope(s), on the same day this declaration was executed, with delivery fees fully provided for at 2049 Century Park East, #2100 Los Angeles, California, in the ordinary course of business.

Executed on November 29, 2006 at Los Angeles, California

☐ **(STATE)** I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

☒ **(FEDERAL)** I declare that I am employed in the office of a member of the Bar of this Court at whose direction the service was made. I declare under penalty of perjury under the laws of the United States of America that the above is true and correct.


Carolyn Simanian

ATTACHED SERVICE LIST

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